

## **REMARKS**

### **Status of the Claims**

Claims 1-21 were previously pending and at issue. Claim 1 has been amended, support for which can be found, for example, in claim 18 as originally filed. Claims 10, 13, and 19 have been amended to correct notational and typographical errors. No new matter has been added by these amendments.

Claims 1-21 are pending and at issue.

### **Rejections Under 35 U.S.C. § 112, first paragraph**

Claim 14 stands rejected as failing to comply with the written description requirement. The Examiner states that the process of preparing pentostatin from pentostatin aglycone is not described in the specification.

Claim 14 was part of the application as-filed, and there is a strong presumption that an adequate written description of the claimed invention is present in the application as-filed. *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976). The MPEP instructs that rejection of an original claim for lack of written description should be rare. See MPEP § 2163.03. Further, what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

Although the conversion of pentostatin aglycone to pentostatin is well known to one of ordinary skill, it was described in detail in the specification. For example, on page 7 in the first paragraph of the summary of the invention, applicants state that pentostatin aglycone is “an intermediate suitable for glycosylation to give pentostatin (Ia).” Also on page 16, last paragraph, applicants state that aglycone is suitable for glycosylation to form pentostatin. On page 3 and again on page 5 of the application, applicants describe a prior art synthesis technique which involves

synthesis of pentostatin from pentostatin aglycone (see page 3, scheme 1, steps 3 and 4, and accompanying text and page 5, lines 10 -13 describing the Hosmane scheme).

Accordingly, the process of preparing pentostatin from pentostatin aglycone is adequately described in the specification. Applicants respectfully request that the rejection be withdrawn.

**Rejections Under 35 U.S.C. § 112, second paragraph**

Claims 1-21 stand rejected as indefinite.

The Examiner states that the terms "pentostatin analog", "aglycone", "aglycone analog", "succinonitrile derivative", and "DMT derivative" are indefinite. Applicants respectfully submit that these terms are clear to a person of ordinary skill in the art when read with the specification as-filed, and request reconsideration in view of the below remarks:

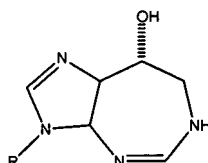
***(a) "pentostatin analog"***

The term pentostatin analog is defined on page 20, line 8 of the application, and refers to pentostatin molecules with a modified sugar moiety or compounds in which one or more of the substituents of the seven member aglycone ring of pentostatin have substitutions or one of the ring members themselves are replaced with a different atom.

Examples of pentostatin molecules with a modified sugar moiety are described throughout the specification, including page 13 in which the oxygen atom in the sugar moiety is replaced with a sulfur atom, a NH group, or a CH<sub>2</sub> group. These compounds refer to thiopentostatin, aza-pentostatin, and carbo-pentostatin respectively. The 5-member sugar ring of pentostatin may also be based, for example, on arabinose, xylose, ribose, lyxose glucose, galactose, manose, gulose, idose, talose, altrose, allose, fructose, sorbose or tagatose instead of deoxyribose.

**(b) "pentostatin aglycone"**

The term "pentostatin aglycone" refers to the 5:7 ring system nucleobase of pentostatin, without the sugar moiety. More particularly pentostatin aglycone refers to the following entity:



in which R is a removable protecting group (see e.g., page 7, first paragraph of the Summary of the Invention). As explained above, a pentostatin aglycone can undergo glycosylation to yield pentostatin.

**(c) "aglycone analog"**

The term "pentostatin aglycone analog" refers to compounds in which one or more of the substituents of the seven member ring are substituted, or are themselves replaced with a different atom (see definition on page 20). For example, the carbon atom between the two nitrogen atoms may be substituted or replaced with a different atom (e.g., a sulfur atom).

**(d) "succinonitrile derivative"**

To advance prosecution, claim 1 has been amended to recite that the succinonitrile derivative has an amine group bound to the second carbon and a -OR group bound to the third carbon, wherein R is a protecting group.

**(e) "DMT derivative".**

DMT (aka Dimethoxytrityl) compounds have a dimethoxy trityl group, and a fourth group such as chlorine to form, for example, DMT-chloride (see Exhibit A) or an -OR group to form a DMT-ether (see Exhibit B). "DMT-derivative" refers to entities without at least a portion of

the fourth group such that the compound is univalent. This is a common abbreviation for an alcohol protecting group in organic chemistry and would be understood by persons of ordinary skill in the art.

Claim 10 has been rejected as indefinite. The Examiner states that it is not known what is meant by the second definition of R, and it is not understood what is meant by "hexoses" under the formula. Claim 10 has been amended to include different notations for the various R groups within this claim, and to remove the word "hexoses".

Claims 18-21 stand rejected as indefinite. The Examiner notes that it is now known what is meant by "substituted imidazole" in claim 18 and the recitation "to form a substituted imidazole compound" lacks antecedent basis in claim 19. The recitation "'to form a substituted imidazole compound" should have been recited in claim 18 instead of claim 19 (see claim 1). Claim 18 has been amended to correct this typographical error.

Applicants submit that the term "substituted imidazole compound" in claim 18, as amended is clear, in view of the reactants that precede this recitation in the claim.

In view of the above amendment, applicant believes the pending application is in condition for allowance. If the Examiner believes that an interview would be helpful to pass this application to allowance, she is respectfully requested to contact the undersigned counsel.

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Respectfully submitted,

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